

**UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA**

STRYKER SPINE, Zi de Marticot, Gestas,
France F-33610; JOHN CARBONE, 20 Westspring
Way, Lutherville, Maryland 21093; AARON
MARKWORTH, 635 Hamburg Turnpike, Pompton
Lakes, New Jersey 07442; MICHAEL HORAN,
45 Sycamore Avenue, Charleston, South
Carolina 29407; and YVES CROZET, 76 Oak Ridge
Road, Ramsey, New Jersey 07446,

Plaintiffs,

v.

BIEDERMANN MOTECH GMBH,
Berta-Suttner-Strasse 23, VS-Schwenningen,
Germany 78054; DEPUY SPINE, INC.,
325 Paramount Drive, Raynham,
Massachusetts 02767; LUTZ BIEDERMANN, Am
Schaförsteig 8 D-78048, VS-Villingen, Germany; and
JURGEN HARMS, Im Zeltyvogel 14 D-76227,
Karlsruhe, Germany.

Defendants.

Civil Action No.

**COMPLAINT PURSUANT
TO 35 U.S.C. § 146**

Case: 1:08-cv-01827
Assigned To: Kollar-Kotelly, Colleen
Assign. Date: 10/24/2008
Description: General Civil

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Plaintiffs, by their undersigned attorneys, as and for their complaint in accordance with
35 U.S.C. § 146, allege as follows:

NATURE OF THE ACTION, JURISDICTION, AND VENUE

1. This action is a request for judicial review of a series of decisions by personnel of
the Patent and Trademark Office ("PTO") in charge of interferences, in which the PTO
is authorized to decide which of competing groups of inventors were first to invent similar
claims in two patent applications. However, the PTO is also empowered to decide other
important issues in an interference relating to whether either party is entitled to obtain or retain
patent claims that were previously found to be allowable in ex parte proceedings. In this case,

EXHIBIT 2005

the PTO repeatedly failed to provide fair, meaningful, and substantive consideration of the important issues committed to it. In numerous instances, important decisions were made arbitrarily and capriciously without plaintiffs having been given a fair opportunity to be heard. In those instances in which the PTO actually addressed substantive matters, the PTO failed to properly consider evidence and arguments and manifestly reached the wrong conclusion. The net result is that if the PTO's decision is allowed to stand, defendants herein would be awarded patent claims to which they are manifestly not entitled on multiple grounds.

2. This is a civil action in a case of an interference brought pursuant to 35 U.S.C. § 146. As more particularly set forth herein, plaintiffs are party to an interference, namely, Patent Interference No. 105,578 (JL) (hereinafter "the Interference") and are not satisfied with the decisions of the Board of Patent Appeals and Interferences (hereinafter "the Board") in connection with the Interference.

3. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1338(a) and 35 U.S.C. § 146.

4. This Court has personal jurisdiction over defendants, and venue is proper in this Judicial District, pursuant to 35 U.S.C. § 146.

PARTIES

5. Plaintiff Stryker Spine is a corporation organized and existing under the laws of France, having an office and place of business at Zi de Marticot, Cestas, France, F-33610.

6. Plaintiff John Carbone is an individual residing at 20 Westspring Way, Lutherville, Maryland 21093

7. Upon information and belief, Plaintiff Aaron Markworth is an individual residing at 635 Hamburg Turnpike, Pompton Lakes, New Jersey 07442.

8. Upon information and belief, Plaintiff Michael Horan is an individual residing at 45 Sycamore Avenue, Charleston, South Carolina 29407.

9. Plaintiff Yves Crozet is an individual residing at 76 Oak Ridge Road, Ramsey, New Jersey 07446.

10. The plaintiffs, John Carbone, Aaron Markworth, Michael Horan, and Yves Crozet (sometimes collectively referred to as "Carbone *et al.*") are the inventors of U.S. Patent No. 6,974,460 (hereinafter "the '460 Patent"), entitled "BIASED ANGULATION BONE FIXATION ASSEMBLY."

11. Plaintiff Stryker Spine is the owner by assignment of all right, title, and interest in the '460 Patent, and is the real party in interest with regard to the '460 Patent.

12. Upon information and belief, defendant Biedermann Motech GmbH is a corporation organized under the laws of Germany having an office and place of business at Berta-Suttner-Strasse 23, VS-Schwenningen, Germany 78054.

13. Upon information and belief, defendant DePuy Spine, Inc. is a corporation organized and existing under the laws of the State of Ohio, having an office and place of business at 325 Paramount Drive, Raynham, Massachusetts 02767, and is an affiliate of Johnson & Johnson of New Brunswick, New Jersey.

14. Upon information and belief, defendant Lutz Biedermann is a citizen of Germany, residing at Am Schaforsteig 8 D-78048, VS-Villingen, Germany.

15. Upon information and belief, defendant Jurgen Harms is a citizen of Germany, residing at Im Zeltyvogel 14 D-76227, Karlsruhe, Germany.

16. Defendants Biedermann and Harms (sometimes collectively referred to as "Biedermann *et al.*") are named as the inventors in U.S. Patent Application No. 10/763,431 (hereinafter "the '431 Application") entitled "BONE SCREW."

17. Upon information and belief, defendant Biedermann Motech GmbH is the assignee of the '431 Application and is a real party in interest in connection with the '431 Application.

18. In response to a standing order in the Interference requiring the parties to identify the real party in interest, defendant DePuy Spine, Inc. has been identified by defendants as the exclusive licensee of the '431 Application and, upon information and belief, is a real party in interest in connection with the '431 Application.

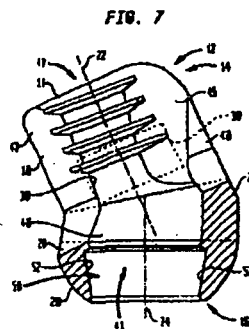
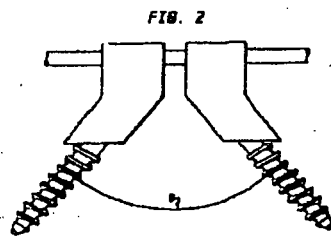
BACKGROUND

The Competing Patent And Patent Application

19. The '460 Patent issued on December 13, 2005, out of U.S. Patent Application No. 10/091,068 ("the '068 Application"), and was the subject of a Certificate of Correction dated April 18, 2006. The '068 Application claimed the benefit of, and was entitled to the benefit of, Provisional Application No. 60/322,042, filed on September 14, 2001.

20. The '460 Patent has 39 claims, of which claims 1, 18, 24, 33, and 38 are independent.

21. Claim 1 of the '460 Patent is directed to an embodiment of a bone fixation assembly having a coupling element with a pair of bores, one of which is biased with respect to the other, such that the central axes of the two bores intersect. Claim 1 also requires a seat at the lower end of the coupling element and an anchoring element with a head in contact with the seat. This embodiment is exemplified by Figures 2 and 7 of the '460 Patent as follows:



In the embodiment of Fig. 7, the first bore 40 has a first longitudinal axis 22 and the second bore 41 has a second longitudinal axis 24, and these two axes intersect in the manner shown therein. In Figure 2, in addition to these two biased bores, an embodiment is shown in which the upper and lower ends are disposed in parallel planes.

22. Claim 18 of the '460 Patent is directed to a bone fixation assembly with a coupling element including only at least one bore and where the upper and lower ends thereof define planes which intersect one another, as opposed to the upper and lower ends being parallel to each other, as in Figure 2 above, as well as an anchoring element and a U-shaped opening in the coupling element as defined therein. By virtue of at least the requirement of the upper and lower ends defining planes which intersect one another, at least certain embodiments of the '460 Patent, such as the embodiment of Figure 2, do not come within the scope of claim 18.

23. The '431 Application was filed on January 22, 2004, and claimed to be a continuation of Application No. 10/037,698, filed on November 9, 2001, which claimed priority from German Application No. 10055888.7, filed on November 10, 2000, and German Application No. 10065397.7, filed on December 27, 2000.

24. Each of the embodiments shown in the specification and drawings of the '431 Application includes a single bore, or bores having the same axis or colinear axes. None of

the embodiments disclosed in the specification and drawings of the '431 Application include bores having first and second longitudinal axes which intersect with each other. Consequently, none of the embodiments disclosed in the specification and drawings of the '431 Application come within the scope of claim 1 of the '460 Patent.

25. The specification and drawings of the Biedermann *et al.* '431 Application and its priority applications fail to provide both written description and enabling disclosure support with regard to the claims of that application corresponding to what would later be described as Carbone *et al.*'s proposed Count 2, namely claims 6-10, 12, 13, 17, 18, 20, 21, 28-32, 34, 35, 40-42, 61, and 62 of the '431 Application.

26. The subject matter of the claims of the Biedermann *et al.* '431 Application corresponding to what would later be described as Carbone *et al.*'s proposed Count 3, namely claims 22-24, 26, 27, and 33 of the '431 Application, is unpatentable over the prior art under 35 U.S.C. §§ 102 and 103. Thus, none of the claims of the Biedermann *et al.* '431 Application are patentable to Biedermann *et al.*

The Declaration Of The Interference

27. On October 10, 2007, the Board declared the Interference between plaintiffs Carbone *et al.* as the inventors of the '460 Patent and defendants Biedermann *et al.* as the named inventors of the '431 Application.

28. In the Declaration of Interference, the '431 Application was accorded the benefit of German Application No. 10055888.7, filed November 10, 2000, and the '460 Patent was accorded the benefit of Provisional Application No. 60/322,042, filed September 14, 2001. Accordingly, defendants Biedermann *et al.* were declared the Senior Party to the Interference, and plaintiffs Carbone *et al.* were declared the Junior Party.

29. In the Declaration of Interference, the single count of the Interference was identified by the Board as "claims 1, 18, 24, 33, or 38 of the '460 Patent, or claims 6, 18, 28, 33, or 35 of the '431 Application." On December 6, 2007, the Board issued a Redecclaration of the Interference in which Count 1 was revised by replacing Biedermann *et al.*'s claim 18 with Biedermann *et al.*'s claim 22.

30. By virtue of the single count of the Interference being defined to include 10 claims, including claims directed to two separate and patentably distinct inventions, such as claims 1 and 18 of the '460 Patent, the count as initially declared by the Board included claims which were not overlapping in scope, and which raised different issues as to compliance with 35 U.S.C. § 112, as well as different issues of patentability under 35 U.S.C. §§ 102 and 103.

31. In the Redecclaration of Interference, the claims of the parties which were said to correspond to Count 1 were claims 1-39 of the '460 Patent and claims 6-10, 12, 13, 17, 18, 20-24, 26-35, 40-42, 61, and 62 of the '431 Application. No claims of either the '460 Patent or the '431 Application were held in the Declaration of Interference to not correspond to Count 1 and to not be involved in the Interference.

32. None of the claims of the '431 Application which were said to correspond to Count 1 of the Interference appeared in any of the applications upon which the '431 Application claims priority, namely German Application No. 10055888.7, filed November 10, 2000, German Application No. 10065397.7, filed December 27, 2000, and U.S. Patent Application No. 10/037,698, filed November 9, 2001. Each of the claims of the '431 Application which were said to correspond to Count 1 of the Interference had been copied, at least in substantial measure, from the '460 Patent.

The API's Refusal To Permit Carbone *et al.* To File Motions

33. The Declaration of Interference directed the parties to file a list of the motions the party intends to file no later than four business days prior to a conference call that was scheduled for 1:00 p.m. on December 5, 2007.

34. On November 29, 2007, both parties filed lists of proposed motions. The description of the motions which Biedermann *et al.* expressed its intention to file read in its entirety as follows:

1. To deny the benefit of Carbone's provisional application Serial No. 60/322,042 granted in the Declaration of this interference as to the count.
2. For the benefit of Biedermann's German Application No. 100 65 397.9, filed December 27, 2000.
3. For judgment of priority of invention against Carbone.

35. Also on November 29, 2007, Carbone *et al.* submitted a list of motions it proposed to file which read as follows:

1. Carbone Miscellaneous Motion 1 (No Interference in Fact) based on Biedermann's lack of support for the invention of the count;
2. Carbone Miscellaneous Motion 2 (to redefine the interfering subject matter) proposing a substitute count;
3. Carbone Miscellaneous Motion 3 (for judgment based on prior art) based on the unpatentability of the count;
4. Carbone Miscellaneous Motion 4 (to designate Carbone claims not corresponding to the proposed new substitute count).

36. At 1:02 p.m. on November 30, 2007, the Board transmitted via e-mail an order which noted that both parties had filed their respective proposed motions list. The order went on to state:

Junior Party Carbone's proposed motions list, however, is so vague as to be not useful for reasonable preparation of the scheduled telephone conference call on December 5, 2007. Accordingly, junior party's proposed motions list is herein dismissed. It is:

ORDERED THAT JUNIOR PARTY Carbone has until the end of today, November 30, 2007, to file a revised proposed motions list which specifically explains why in the junior party's view, there is (1) no interference in fact, (2) why a substitute count is needed and what the junior party proposes as the substitute count, (3) which claims of the senior party are under attack for unpatentability and the specific grounds of unpatentability, and (4) which claims of the senior party do not correspond to junior party's proposed substitute count and why.

The foregoing order said nothing regarding the specificity, or lack thereof, of the proposed motions list filed by the Senior Party Biedermann.

37. On November 30, 2007, at approximately 3:57 p.m., counsel for Carbone *et al.* filed via e-mail a revised list of proposed motions which identified the proposed motions as follows:

1. Motion To Declare No Interference in Fact. Count 1 was initially based, *inter alia*, upon claims 1, 24 and 38 of Carbone's U.S. Patent No. 6,974,460 ("Carbone's '460 Patent"), as well as claims 6, 28 and 35 of Biedermann's Application. Each of these claims, however, is directed to an invention ("Invention 1") which differs from and is patentable over the invention disclosed in Biedermann's Application, as well as from the invention claimed in claims 18 and 33 of Carbone's '460 Patent, and claims 22¹ and 33 of Biedermann's Application ("Invention 2"). Thus, there is "no interference in fact" between Invention 1 and Invention 2, which are patentably distinct from each other.

2. Motion To Redefine the Interfering Subject Matter. One consequence of the above motion, whatever it is ultimately labeled, should be to provide a substitute count which is basically directed to Invention 2. That count would correspond to claims 18 and 33 of Carbone's '460 Patent and claim 22 of Biedermann's Application, but would not correspond to claims 1, 24, and 38 of Carbone's '460 Patent nor claims 6, 28, and 35 of Biedermann's Application (Invention 1).

3. Motion based on the unpatentability of the count to Biedermann. Count 1 is unpatentable to Biedermann because Biedermann's Application is entirely lacking of support for claims 1, 24 and 38 of Carbone's '460 Patent and claims 6, 28 and 35 of Biedermann's Application (*i.e.*, Invention 1). Count 1 is thus unpatentable to Biedermann under 35 U.S.C. § 112. The substitute count referred to in Paragraph 2 above is unpatentable over the prior art under 35 U.S.C. §§ 102 and 103 (c).

4. Motion specifying that a number of additional claims in Carbone's '460 Patent do not correspond to the proposed substitute count discussed in Paragraph 2 above. Thus, in addition to claims 1-17, 24-32, and 38-39 of Carbone's '460 Patent, claims 34-37 thereof also do not correspond to the proposed substitute count referred to in Paragraph 2 above, again because they are patentably distinct therefrom.

¹ The count is believed to mistakenly refer to Biedermann's claim 18.

38. On December 5, 2007, a telephone conference call had been scheduled and was conducted by Administrative Patent Judge Jameson Lee (hereinafter "the APJ"), along with lead counsel and back-up counsel for Carbone *et al.*, Arnold H. Krumholz and Kevin M. Kocun, respectively, and counsel for Biedermann *et al.*, Barry Bretschneider. The December 5, 2007 conference call was neither transcribed nor recorded.

39. Prior to the conference, counsel for Carbone *et al.* was prepared to discuss the proposed motions identified in the list previously filed, but was not prepared to fully argue the merits of each motion, based upon counsel's understanding of the applicable rules including Standing Order ("SO") 104. 2.1 and SO 204.

40. The APJ initiated the conference by immediately stating that he could not understand the motions list filed by Carbone *et al.*, and that it was not the APJ's proper function to assist counsel in presenting their motions. The APJ requested that Carbone *et al.*'s counsel therefore explain its list to opposing counsel.

41. Counsel for Carbone *et al.* then did so, explaining that, in view of the nature of the sole count in this interference, which included ten alternative claims, and considering that these claims were directed to two entirely different inventions, which were not overlapping in scope, counsel for Carbone *et al.* believed that a motion of no interference in fact was in order. Counsel for Carbone *et al.* also explained that of these two inventions, one was believed to be unpatentable to senior party Biedermann *et al.* under 35 U.S.C. § 112, and the other was believed to be unpatentable over the prior art. It was ultimately agreed that a first motion should be a motion to redefine the interference to include two counts.

42. The APJ responded that the purpose of the motions list was not to "spill our guts all over the paper," and then demanded that counsel for Carbone *et al.* argue the merits of each proposed motion.

43. With respect to the proposed motion under Section 112, counsel for Carbone *et al.* explained that the motion was intended to be made both on the basis of lack of written description and lack of enablement. With respect to lack of enablement, after explaining Carbone *et al.*'s position with respect to the presence of two inventions in the claims of the '460 Patent, counsel for Carbone *et al.* explained that one of these inventions (that of claims 1, 24 and 38) was not disclosed at all in the senior party Biedermann *et al.*'s application.

44. The APJ then specifically required counsel for Carbone *et al.* to address the enablement factors enumerated in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Counsel for Carbone *et al.* explained to the APJ that counsel was not prepared to discuss the specifics of the *Wands* case. The APJ then stated that "you have thirty seconds" to prepare your position. The response provided by counsel for Carbone *et al.* did not satisfy the APJ.

45. On the evening of December 5, 2007, Kevin Kocun, back-up counsel for Carbone *et al.*, received a call from the APJ advising him that Carbone *et al.* was not authorized to pursue a motion on the basis that Biedermann *et al.*'s claims corresponding to the count are unpatentable over the prior art.

46. On December 6, 2007, counsel for Carbone *et al.* received a further call from the APJ indicating that he wished to have a further conference call for the purpose of finalizing his rulings so that he could prepare the necessary order. Counsel for Carbone *et al.* again took that opportunity to explain to the APJ that counsel for Carbone *et al.* had not been fully prepared to argue the entire merits of the motions on December 5, 2007, and requested an opportunity to do

so. The APJ appeared to agree to this, stating that counsel for Carbone *et al.* could bring it up in the phone conference. Within the next half hour, the APJ advised that he had contacted opposing counsel, that he was prepared to proceed with a further conference call, and did so.

47. The December 6, 2007 conference call was neither transcribed nor recorded. Counsel for Carbone *et al.* began that conference call by attempting to again argue the merits of the motion based on lack of enablement and was now prepared to specifically discuss the *Wands* factors. The APJ immediately asked "why are you arguing the merits?" The APJ then made clear to counsel for Carbone *et al.* that a decision refusing to allow that motion to be made had already been made, even though an order had not yet been entered. The telephone conference then proceeded with respect to a proposed motion based on unpatentability of Biedermann *et al.*'s claims over the prior art.

48. On December 6, 2007, the Board issued an order in the Interference (hereinafter "the December 6, 2007 Order") which followed the two foregoing conference calls between counsel for Carbone *et al.*, counsel for Biedermann *et al.*, and the APJ. The December 6, 2007 Order went on to state that counsel for Carbone *et al.* had explained that Count 1 included two patentably distinct inventions, one represented by Carbone *et al.*'s patent claims 1, 24, and 38 and Biedermann *et al.*'s application claims 6, 28, and 35, and a second invention represented by Carbone *et al.*'s patent claims 18 and 33 and Biedermann *et al.*'s application claims 22 and 33. The December 6, 2007 Order further noted that Carbone *et al.*'s counsel had indicated that Carbone *et al.* wished to file a motion to separate existing Count 1 into two counts, namely, Count 2 defined as Carbone *et al.*'s claims 1, 24, or 38 or Biedermann *et al.*'s claims 6, 28, or 35, and Count 3 including Carbone *et al.*'s claims 18 or 33 and Biedermann *et al.*'s claims 22 or 33,

and that the claims corresponding to each count would be those which are identical to one of the alternative claims in the count or dependent therefrom.

49. The December 6, 2007 Order further noted that counsel for Carbone *et al.* had explained Carbone *et al.*'s view that Biedermann *et al.*'s application did not have written description support and an enabling disclosure.

50. The December 6, 2007 Order also recited that counsel for Carbone *et al.* had explained that Carbone *et al.*'s view that the Biedermann *et al.* application did not have written description support or an enabling disclosure for claims which would correspond to proposed Count 2. While the Order acknowledged that Carbone *et al.*'s counsel had explained that "Biedermann's specification does not describe or disclose the subject matter of these claims" and that "there was no description in [Biedermann *et al.*'s] specification," the APJ asserted that Carbone *et al.*'s counsel was unable to articulate any reasoning responsive to the APJ's inquiry regarding enablement.

51. In the December 6, 2007 Order, the APJ ruled that Carbone *et al.* were not authorized to file a motion asserting that any claims of Biedermann *et al.* were unpatentable under 35 U.S.C. § 112, first paragraph, for lack of an enabling disclosure. The APJ stated in this regard:

The integrity of the administrative process would be undermined by allowing a party to proceed with a motion without having any reasonable basis to do so, only on the hope that sometime later, before the motion is due, the party will somehow figure out a basis for the motion.

52. The December 6, 2007 Order further noted that Carbone *et al.* had expressed the belief that Biedermann *et al.*'s claims that would correspond to Count 3, as well as Carbone *et al.*'s claims which would correspond to Count 3, were unpatentable over the prior art. The APJ further noted that when the APJ had inquired as to the basis of unpatentability, counsel for

Carbone *et al.* had identified one U.S. patent, namely U.S. Patent No. 6,299,614, and four French patents, namely French Patent Nos. 2740674, 2693365, 2789293, and 2734471. The Order further noted that when asked if he could specifically identify "any other reference," counsel for Carbone *et al.* indicated that the five identified references would be sufficient.

53. The December 6, 2007 Order further noted that Carbone *et al.*'s counsel had indicated that Carbone *et al.* would not be filing a motion regarding priority as to any existing or proposed count in the Interference. The APJ further recited that counsel for Carbone *et al.*

... maintained, however, that the junior party should not lose on priority with respect to Count 2 if the junior party's motion attacking all of senior party's claims corresponding to Count 2 as unpatentable for lack of written description is granted. The patent judge agreed with that position and Mr. Bretschneider [counsel for Biedermann *et al.*] did not indicate disagreement.

54. The December 6, 2007 Order further noted that because of the concession of priority by Carbone *et al.*, the proposed challenge to the claims in proposed Count 3 by Carbone *et al.* was "not necessary in interference in light of [Carbone *et al.*'s] concession of priority and thus is not authorized."

55. The December 6, 2007 Order further noted that during a follow-up telephone conference call earlier that day, counsel for Carbone *et al.* was provided another opportunity to urge the Board to authorize Carbone *et al.* to file a motion to attack the Senior Party's claims that would correspond to proposed Count 3 on the basis of prior art despite Carbone *et al.*'s concession of priority. The December 6, 2007 Order noted that the APJ heard counsel's arguments but still considered the motion unnecessary in that Carbone *et al.* had conceded priority.

Carbone *et al.*'s Request For Rehearing Regarding Enablement

56. On December 20, 2007, Carbone *et al.* filed a timely request for rehearing of the December 6, 2007 Order insofar as it stated that Carbone *et al.* was not authorized to file a

motion asserting lack of an enabling disclosure (hereinafter "the First Request for Rehearing"). This request for rehearing was supported by an accompanying declaration of Arnold H. Krumholz, Esq.

57. The First Request for Rehearing urged that the denial of the right of Carbone *et al.* to make a motion directed to lack of enablement was an abuse of discretion because the facts that were presented to the APJ were sufficient to warrant proceeding with a clearly meritorious motion, and that the manner in which the APJ denied Carbone *et al.* the right to make that motion lacked even a minimal degree of fairness.

58. The First Request for Rehearing explained that the motions which Carbone *et al.* had proposed to make were necessitated by the fact that the single count of the Interference as declared was defined by 10 claims which included claims directed to two separate inventions, including counts which were not overlapping in scope, such as claims 1 and 18 of the Carbone *et al.* '460 Patent.

59. The First Request for Rehearing further urged that even where an interference is conducted over a "phantom" count (*i.e.*, a count which does not appear as an actual claim within either contested application or patent), the important fact was that proof of priority with respect to an embodiment within the scope of a count suffice to establish priority over the patentable invention in question, and that this was clearly not the case with regard to the different inventions encompassed, for example, in claims 1 and 18 of the Carbone *et al.* '460 Patent.

60. The First Request for Rehearing further urged that apart from the lack of fairness in the proceedings which had resulted in the December 6, 2007 Order, the APJ had before him sufficient facts to at least warrant granting permission for Carbone *et al.* to file a motion to have certain of the Biedermann *et al.* claims held to be unpatentable for lack of enablement. This

included the fact that none of the embodiments disclosed in the Biedermann *et al.* '431 Application fall within the scope of claim 1 of the Carbone *et al.* '460 Patent, and the fact that embodiments of the '460 Patent, such as Figure 2 thereof, do not fall within the scope of either of Biedermann *et al.*'s claims 22 or 33.

61. The First Request for Rehearing further urged that since counsel for Carbone *et al.* had argued that the Biedermann *et al.* '431 Application specification did not describe or disclose the subject matter of claim 1 of the '460 Patent, the absence of any disclosure whatsoever meant that there could not possibly be sufficient disclosure to enable one skilled in the art to make the subject product, and that the facts urged by counsel for Carbone *et al.* were sufficient to warrant the right to bring the motion in the first instance.

62. The First Request for Rehearing further urged that the proceedings which led to the December 6, 2007 Order lacked a modicum of fairness which resulted in the possibility of counsel's client being stripped of basic rights to make such motions. This included an assertion that the APJ's unwillingness to allow counsel for Carbone *et al.* on December 6, 2007, to augment his prior position as set forth during the 30 seconds granted to counsel on December 5, 2007, was unfair.

63. The First Request for Rehearing further urged that since the Board's SO 104.2.1 specifically authorizes the Board to allow a party to file a motion that has not previously been listed, it was unfair to deny counsel any leeway in attempting to justify and explain a proposed motion which had in fact been listed.

64. It was further urged in the First Request for Rehearing that the APJ's demand that counsel for Carbone *et al.* argue the factors set forth in *In re Wands* was improper, since

subsequent binding precedent made clear that a consideration of enablement did not require consideration of all the *Wands* factors, which were deemed illustrative but not mandatory.

65. It was further urged in the First Request for Rehearing that since the APJ had authorized Carbone *et al.* to file a motion based upon the assertion that Biedermann *et al.*'s claims lack written description under 35 U.S.C. § 112, no undue burden would be created by allowing Carbone *et al.* to concurrently move on the basis of lack of enablement, in light of the relationship between enablement and written description.

66. Still further, in the First Request for Rehearing, Carbone *et al.* made reference to the fact that Biedermann *et al.* would have the burden of establishing that its application complies with 35 U.S.C. § 112.

Carbone *et al.*'s Request For Rehearing Regarding Unpatentability Over The Prior Art

67. On December 20, 2007, Carbone *et al.* filed a separate request for rehearing of the December 6, 2007 Order insofar as it stated that Carbone *et al.* was not authorized to file a motion asserting unpatentability over the prior art (hereinafter "the Second Request for Rehearing").

68. In the Second Request for Rehearing, Carbone *et al.* urged that the December 6, 2007 Order was contrary to current common practices and intentions of the Board, and pointed out that the Board and the Court of Appeals for the Federal Circuit had made clear that if patentability was fairly placed at issue in an interference proceeding, it will be determined.

69. In the Second Request for Rehearing, Carbone *et al.* also urged that the APJ's refusal to allow Carbone *et al.* to file a motion directed to unpatentability was contrary to other motions to be filed by Carbone *et al.* which had been authorized in the December 6, 2007 Order. This included Carbone *et al.*'s proposed motion to redefine the Interference by replacing the current count with proposed Counts 2 and 3 and, if this motion were to be granted, a contingent

motion against all of the Biedermann *et al.* claims which would correspond to proposed Count 2 for lack of written description support under 35 U.S.C. § 112, first paragraph, which was an attack on the patentability of the claims associated with proposed Count 2. Thus, the Second Request for Rehearing urged that since the Board may be considering the patentability of the claims in one proposed count under Section 112, the Board should also consider the patentability of claims in the other proposed count under 35 U.S.C. §§ 102 and 103.

70. The Second Request for Rehearing further urged that the APJ's suggestion during one or more of the December 5 and 6, 2007 conference calls that Carbone *et al.* assert prior art references in a separate proceeding, such as reexamination, was contrary to Congress's intent in creating a unified, streamlined board designed to consider issues of both priority and patentability. The Second Request for Rehearing further urged that patentability under Section 112 on the one hand and under Sections 102 and 103 on the other hand are almost always addressed concurrently during prosecution of an application, and that splitting up these different grounds for arguing patentability in the Interference was inefficient and contrary to the charge of the Board.

The Board's January 22, 2008 Decision Denying Rehearing

71. On January 22, 2008, a panel of three Administrative Patent Judges issued a decision denying rehearing in connection with both of the requests for rehearing filed by Carbone *et al.* (hereinafter "the January 22, 2008 Order").

72. Upon information and belief, at least one of the foregoing three Administrative Patent Judges was appointed after March 2000 by the Director of the PTO, such that the appointment was unconstitutional in violation of Article II § 2, clause 2 of the U.S. Constitution, which requires that appointments be made by the President, the courts, or heads of departments.

The Director of the PTO was at no time a head of the Department of Commerce or any other department of the United States Government.

73. In the January 22, 2008 Order, the Board noted that in the conference call held on December 6, 2007, counsel for Carbone *et al.* had attempted to continue discussing its request for permission to file a motion for judgment based upon lack of enabling disclosure. The Order went on to state that the APJ "declined to revisit the issue on the ground that it had already been decided the previous day."

74. In the January 22, 2008 Order, in addressing the argument by Carbone *et al.* that they had been deprived of a minimal degree of fairness, based in part on their counsel having been given only 30 seconds to formulate a position as to why the Biedermann *et al.* application lacked an enabling disclosure under the criteria set forth in *In re Wands*, the Board concluded that counsel for Carbone *et al.* had eight weeks before the conference call began to prepare and formulate a theory, such that the argument regarding fairness by Carbone *et al.* was rejected by the Board.

75. With further regard to the issue of enabling disclosure, in the January 22, 2008 Order, the Board repeatedly characterized the position advanced by Carbone *et al.* as a contention that because there is no "description" in the specification of the subject matter claimed, there could not be sufficient disclosure to enable one skilled in the art to make the product at issue, and rejected this purported argument on the basis that enablement and written description are separate and distinct. The Board reached this conclusion notwithstanding the fact that the only evidence of record as to what arguments had been advanced by Carbone *et al.*, namely the foregoing Declaration of Arnold H. Krumholz, made clear that the position of Carbone *et al.* was that the Biedermann *et al.* '431 Application had no "disclosure" whatsoever,

as contrasted with the Board's characterization of Carbone *et al.* having urged that there was no "description."

76. In the January 22, 2008 Order, the Board stated that after being directed to some factors which would be pertinent to an enabling disclosure inquiry, in apparent reference to the APJ's citation of *In re Wands*, counsel for Carbone *et al.* still purportedly could articulate nothing beyond the general assertion that the Biedermann *et al.* specification did not have a written description for the claimed invention. This was in apparent reference to the 30 seconds that were given to Carbone *et al.*'s counsel to respond to the APJ's request after the APJ's citation of *In re Wands* during the December 5, 2007 conference call.

77. In the January 22, 2008 Order, the Board held that Carbone *et al.* had been mistaken in suggesting that the burden would be on Biedermann *et al.* to establish compliance with the enablement requirement, and held that lack of an enabling disclosure was an issue on which Carbone *et al.* would ultimately bear the burden of proof. The Board reached this conclusion without reference to the fact that notwithstanding Biedermann *et al.*'s status as Senior Party, because Biedermann *et al.* had copied the claims at issue, the burden was on Biedermann *et al.* to establish compliance with Section 112.

78. In the January 22, 2008 Order, the Board concluded that it was "not necessary to consider any lack of enabling disclosure" based on the Board's premise that Carbone *et al.*'s theory regarding enablement was entirely dependent on its position regarding written description. Apart from the premise of that conclusion, the Board's foregoing statement did not address the possibility that while the absence of written description support would doom Biedermann *et al.*'s compliance with the enablement requirement, the possible presence of written description

support would not necessarily determine whether the Biedermann *et al.* '431 Application had an enabling disclosure.

79. In the January 22, 2008 Order, in connection with the arguments regarding fairness raised by Carbone *et al.*, the Board stated, "a substantial portion of the [December 5, 2007] conference call which lasted well over an hour was devoted to the [APJ's] probing Carbone's basis for asserting that Biedermann's claims are unpatentable under 35 U.S.C. § 112, first paragraph, for lack of an enabling disclosure." The Board so stated without reference to the fact that the APJ had given counsel for Carbone *et al.* 30 seconds to argue compliance with a Federal Circuit decision which had not previously been discussed in any filing in the Interference.

80. In the January 22, 2008 Order, the Board affirmed the APJ's refusal to "revisit" the issue of enablement in the December 6, 2007 conference call, on the basis that Carbone *et al.* "already had a full and fair opportunity to present his case the previous day"; that Carbone *et al.*'s "recourse" was to file a request for rehearing after a written order is received (presumably in reference to the request for rehearing which the Board was there denying); and that the efficiency of the administrative process would be undermined if any party dissatisfied with a ruling of the APJ can have the issue revisited "at any time without filing a request for rehearing" (presumably in reference to Carbone *et al.*'s attempt to "revisit" the issue one day later after a telephone conference which had neither been recorded nor transcribed).

81. In the January 28, 2008 Order, the Board affirmed the APJ's ruling that it was not necessary to address the patentability of certain of Biedermann *et al.*'s claims over the prior art, as this would "unduly complicate this proceeding and turn it into a pre-grant opposition

proceeding." The Board did so without explaining why that would not be true of any interference in which patentability over the prior art is adjudicated.

82. In the January 22, 2008 Order, the Board apparently acknowledged that under Federal Circuit precedent, it was expected to adjudicate issues of patentability where a record on that issue was fully developed before the Board, but concluded that such rule was inapplicable because no such full record had been developed. The only reason no such full record had been developed at the time of the January 22, 2008 Order was that first the APJ, and then the Board, refused to allow Carbone *et al.* to develop such a full record.

83. Still further, in the January 22, 2008 Order, the Board noted that its rule requiring authorization to file motions came into existence subsequent to the Federal Circuit decisions holding that the Board should adjudicate issues of patentability that have been fully developed before the Board, apparently concluding that the Board's rules overrode decisions of the U.S. Court of Appeals for the Federal Circuit applying a federal statute, namely 35 U.S.C. § 135(a).

84. Finally, in the January 22, 2008 Order, the Board rejected the argument of Carbone *et al.* that the issue of written description and the issue of unpatentability in view of the prior art could be and should be addressed concurrently without undue burden. The Board held in this regard that the two issues "do not share much common ground, particularly over different sets of claims. Per Carbone's own assertion, the different sets of claims are directed to patentably distinct inventions," notwithstanding the fact that these two issues both raised patentability issues, and the Board itself ultimately ruled that the sets of claims were not patentably distinct.

Carbone *et al.* File Their Substantive Motions

85. On February 13, 2008, Carbone *et al.* timely filed what was identified as "Substantive Motion I" to redefine the Interference in accordance with 37 C.F.R.

§ 41.121(a)(1)(i). More particularly, the motion sought to divide Count 1 into two separate proposed Counts 2 and 3. The basis for the motion was that Count 1 included two separate inventions which were patentably distinct from each other, such that it was inappropriate to include such two separate inventions in a single count.

86. In the foregoing motion, Carbone *et al.* proposed that new Count 2 be defined as claims 1, 24, or 38 of the Carbone *et al.* '460 Patent or claims 6, 28, or 35 of the Biedermann *et al.* '431 Application. Carbone *et al.* further proposed that Count 3 be defined as claims 18 or 33 of the Carbone *et al.* '460 Patent or claims 22 or 33 of the Biedermann *et al.* '431 Application.

87. Also on February 13, 2008, Carbone *et al.* timely filed what was identified as "Substantive Motion 2," which was contingent upon the granting of Substantive Motion 1. The relief sought by Substantive Motion 2 was that upon granting of Substantive Motion 1, judgment should be entered against Biedermann *et al.*'s claims corresponding to proposed Count 2, namely claims 6-8, 10, 12, 13, 17, 18, 20, 21, 28-32, 35-42, 61, and 62 of the Biedermann *et al.* '431 Application, were unpatentable for failure to meet the "written description" requirement of 35 U.S.C. § 112, first paragraph.

88. In support of Substantive Motions 1 and 2, Carbone *et al.* filed the Declaration of Charles L. Bush, Jr.

89. Biedermann *et al.* filed no opposition at any time to either of the foregoing Substantive Motions.

90. On February 14, 2008, the APJ issued a decision dismissing Carbone *et al.*'s Substantive Motion 1 as unauthorized on the basis that the motion that as filed did not comport with the December 6, 2007 Order, on the basis that the motion as authorized was required to split

all claims into either proposed Count 2 or proposed Count 3, such that the claims corresponding to those counts would be all claims identical to or dependent from the claims recited as the proposed counts.

91. On February 15, 2008, Carbone *et al.* filed a revised version of Substantive Motion 1, in which claims 4 and 37 of the Carbone *et al.* '460 Patent and claims 9 and 34 of the Biedermann *et al.* '431 Application (originally noted as not corresponding to either Count 1 or Count 2 in the Substantive Motion 1) were noted as corresponding to Count 2.

92. On February 19, 2008, the APJ conducted a telephone conference with counsel, for which a verbatim transcript was prepared. During the foregoing telephone conference, counsel for Biedermann *et al.* urged the APJ to review Carbone *et al.*'s Substantive Motion 2 and conclude that it was so baseless on its face that it could be and should be denied without Biedermann *et al.* filing a substantive opposition. Counsel for Biedermann *et al.* also requested that notwithstanding Substantive Motion 2 being made contingent on granting Substantive Motion 1, the APJ and/or the Board should decide and deny Substantive Motion 2 before considering Substantive Motion 1, as a denial of Substantive Motion 2 would, in Biedermann *et al.*'s view, moot the entire proceeding.

93. During the February 19, 2008 conference call, counsel for Carbone *et al.* urged the APJ to address and decide both motions as a matter of judicial economy so as to avoid further proceedings on remand in the event a decision of the Board was reversed on appeal.

94. During the February 19, 2008 conference call, the APJ and counsel noted certain errors in the designation of claims in Substantive Motion 2, and the APJ indicated that Carbone *et al.* would be permitted to file a revised version of that motion.

95. On the same day as the foregoing telephone conference, the APJ issued an order (hereinafter "the February 19, 2008 Order"). The February 19, 2008 Order denied Biedermann *et al.*'s request to have Carbone *et al.*'s Substantive Motion 2 denied solely on a review of the statement of relief requested therein and the accompanying statement of material facts was denied. The foregoing order further noted that nothing precludes the Board from deciding, on its own, to "pick up" Carbone *et al.*'s Substantive Motion 2 prior to the filing of Biedermann *et al.*'s opposition, and if it is as deficient as Biedermann *et al.* suggests, the Board could decide the motion without the need of an opposition from Biedermann *et al.*

96. The February 19, 2008 Order further stated that Carbone *et al.*'s Substantive Motion 2 incorrectly identified the claims of Biedermann *et al.* that were under attack and ordered Carbone *et al.* to file a revised Substantive Motion 2 to correct such misidentification.

97. On February 21, 2008, Carbone *et al.* filed a revised version of its Substantive Motion 2 in accordance with the February 19, 2008 Order.

98. On April 3, 2008, approximately four business days before Biedermann *et al.* was due to respond to Carbone *et al.*'s Substantive Motions 1 and 2 (and subsequent to a deposition of Carbone *et al.*'s expert witness had been conducted), the APJ issued a further order (hereinafter "the April 3, 2008 Order"). The April 3, 2008 Order made reference to the prior telephone conference of February 19, 2008 and ordered that no opposition to Carbone *et al.*'s Substantive Motions 1 and 2 should be filed until further notice from the Board.

The Board Denies Carbone *et al.*'s Substantive Motions 1 And 2

99. On April 30, 2008, the same panel of three administrative judges that had issued the January 22, 2008 Order issued a Memorandum Opinion and Order denying Carbone *et al.*'s revised Substantive Motions 1 and 2 and concurrently issued a judgment against Carbone *et al.*

ordering that claims 1-39 of the Carbone *et al.* '460 Patent be cancelled (hereinafter "the April 30, 2008 Decision").

100. In the April 30, 2008 Decision, the Board concluded that Charles L. Bush, Jr., who had submitted a declaration in support of Carbone *et al.*'s motions, was qualified to testify as to the knowledge of one skilled in the art in the field of bone fixation assemblies at the time of the invention.

101. The Board also concluded in the April 30, 2008 Decision that Mr. Bush had not offered testimony regarding what the knowledge of one skilled in the art was, nor had he provided evidence that his analysis of Count 1 and the two proposed counts involved consideration of the level of ordinary skill in the art. As a consequence, the Board held that Mr. Bush's testimony was insufficient to prove that Count 1 encompasses two patentably distinct inventions.

102. In the April 30, 2008 Decision, the Board ruled that Carbone *et al.* had failed to provide any meaningful analysis with respect to whether the differences between the two proposed counts are such that at least one would not have been obvious over the other from the perspective of one with ordinary skill in the art.

103. In the April 30, 2008 Decision, the Board further concluded that Mr. Bush had not provided evidence that his analysis of Count 1 and the two proposed counts involved consideration of the lack of ordinary skill in the art.

104. Still further in the April 30, 2008 Decision, the Board stated that Carbone *et al.*'s discussion of the prior art mentioned two patents (including the Metz Patent), both of which were cited in the Carbone *et al.* '460 Patent, but did not discuss the prior art relating to the coupling art in general.

105. In addition to the foregoing, in the April 30, 2008 Decision, the Board concluded that a meaningful discussion regarding the knowledge of a person of ordinary skill or persuasive reasoning based on factual evidence was not presented but merely a naked legal conclusion was asserted.

106. The Board's April 30, 2008 Decision relied on a single prior Board decision, namely, *Pechiney Emballage Flexible Europe v. Cryovac Inc.*, 73 U.S.P.Q.2d 1571 (2004), in support of its contention that Carbone has not made out a *prima facie* case.

107. In its April 30, 2008 Decision, the Board supported its conclusion that Carbone *et al.* failed to consider the differences between the claimed subject matter and the prior art, as required, by stating that Carbone *et al.* did not persuasively distinguish the claims of the two counts, and then went on to analyze a number of elements therein.

108. Still further, in its April 30, 2008 Decision, the Board discussed the fact that while claim 1 of the Carbone *et al.* '460 Patent does not expressly recite that the upper and lower ends of the coupling elements are in intersecting planes, it does not follow that the planes cannot intersect, as required by claim 18 of the Carbone *et al.* '460 Patent.

Carbone *et al.* Requests Rehearing Of The April 30, 2008 Decision

109. On May 30, 2008, Carbone *et al.* filed a timely request for rehearing of the Board's April 30, 2008 Decision pursuant to Board Rule 125(c)(1) (hereinafter "the Final Request for Rehearing").

110. In the Final Request for Rehearing, Carbone *et al.* specifically cited and addressed, *inter alia*, each of the grounds for ruling against Carbone *et al.* set forth in paragraphs 101-108 hereof.

111. The Final Request for Rehearing included at least five specific references to pages and lines of the April 30, 2008 Decision at page 1, line 20; page 2, lines 3 and 8; page 3, line 1; and page 6, line 3.

112. In the Final Request for Rehearing, in addition to the foregoing arguments, Carbone *et al.* addressed the single prior Board decision cited in the April 30, 2008 Decision, argued that it was not binding precedent, and further argued that the decision had been satisfied by Carbone *et al.* even if it were binding precedent.

113. Also in the Final Request for Rehearing, Carbone *et al.* argued that there was an inconsistency between the Board's conclusions with regard to Carbone *et al.*'s Substantive Motion 1 and arguments made by Biedermann *et al.* during *ex parte* prosecution of their '431 Application.

114. Still further, in the Final Request for Rehearing, Carbone *et al.* urged the Board to allow both of Carbone *et al.*'s Substantive Motions 1 and 2 to be fully briefed and decided so that all relevant issues could be reviewed on appeal to minimize the need for further proceedings before the Board and/or in a reviewing Court.

115. Lastly, in the Final Request for Rehearing, Carbone *et al.* challenged the authority of the Board to decide this case, asserting that at least one of the APJs who had decided the case was appointed after March 2000 by the Director of the PTO and that such appointment was unconstitutional under Article II § 2, clause 2, of the United States Constitution which required that such appointments be made by the President, the courts, or the head of a department, and thus did not include the Director of the PTO.

The Board Denies Carbone *et al.*'s Requests For Rehearing

116. On August 27, 2008, the Board issued a decision on rehearing in accordance with Board Rule 125(c) in which it denied the request for rehearing (hereinafter "the August 27, 2008 Final Decision").

117. In the August 27, 2008 Final Decision, the Board concluded that Carbone *et al.*'s Request for Rehearing failed in large part to comply with either 37 C.F.R. § 41.125(c) or Standing Order ¶ 125.2 because, in their Request for Rehearing, Carbone *et al.* provided "the page and line numbers corresponding to the initial panel decision for some, but not all, of [their] challenges, along with a statement as to what Carbone *et al.* believe[s] was overlooked or misapprehended." The Board further noted that Carbone *et al.*'s Request for Rehearing "consistently fails in all instances to provide specific identification of the place where the matter allegedly overlooked or misapprehended by the panel in the initial decision was previously addressed in Motion 1."

118. In view of the foregoing, the Board dismissed Carbone *et al.*'s Request for Rehearing for failing to comply with the rules and the Standing Order. Alternatively, in considering the request on the merits, the Board found it to be unpersuasive and denied the Request for Rehearing.

119. In the August 27, 2008 Final Decision, the Board asserted that Carbone *et al.* in their Revised Motion 1 did not introduce its proposed Count 2 or Count 3 until the tenth page of the motion.

120. In the August 27, 2008 Final Decision, the Board stated that at no point did Carbone *et al.* provide an analysis of the specific elements of Count 2 versus Count 3, the differences between the counts, and why the differences are such that one count would not have

been obvious over the other in view of the knowledge of one of ordinary skill in the art or pertinent prior art known to Carbone *et al.*

121. In the August 27, 2008 Final Decision, the Board concluded that instead of the foregoing, the "thrust" of Carbone *et al.*'s argument in Revised Motion I was that there were two "inventions" in Count I from the perspective of the prior art that preexisted both inventions. The Board further concluded that Carbone *et al.* discussed Invention (1) or Invention (2) without specifically relating the discussion to a proper analysis which treats Invention (1) as prior art to Invention (2), or Invention (2) as prior art to Invention (1) in the context of the elements of the two proposed counts.

122. The Board further stated that, in the proper analysis, the two inventions already constitute the closest prior art to each other. Thus, the Board asserted that the issue which should have been addressed is why the differences are such that one invention would not have been obvious from the other if the other is treated as prior art, and that the issue is not whether each invention defines a different patentable distinction over prior art which preexisted both inventions.

123. In reaching the foregoing conclusions, the Board, in its August 27, 2008 Final Decision, did not make reference to the following discussion in Carbone *et al.*'s Revised Motion I in determining whether Carbone *et al.* had argued that Carbone *et al.* had analyzed obviousness treating Invention (1) as prior art to Invention (2):

If Invention (1) were prior art to Invention (2), Invention (2) would nevertheless be patentable and unobvious over Invention (1), because by creating a pair of angularly disposed channels in the coupling element, and by thus employing a coupling element which has at least a pair of bores, each having separate longitudinal axes which intersect each other, one would be able to achieve greater angulation of the screw member *vis-à-vis* the coupling element, whether or not the ends of the device are parallel to each other. (Bush Decl. ¶ 28.)

Invention (2) thus seeks to maintain or increase the strength of the coupling member by changing the internal geometry of same and thereby providing for more angulation, as well as a lower profile. Thus, a fastener which is placed in the coupling element of Invention (2) is initially in a biased position by virtue of the internal geometry thereof. The axis of the fastener is thus coaxial with that of the lower bore of the coupling element when in its advantageous angulated position. When the fastener is thus subjected to forces tending to pull it away from the coupling element, the fastener is not subjected to torsional forces. The fastener head in the coupling element is also retained in a manner similar to that shown, for example, in the Metz patent. Thus, the greater angulation design of Invention (2) does not reduce the amount of fastener head retained and supported by the coupling element, as is the case with the Biedermann application and Invention (1) when in the angulated position. The strongest possible position of the construct of Invention (2) is exhibited when the fastener is angulated with respect to the coupling element, *i.e.*, the fastener is coaxial with the axis of the lower bore. Moreover, the initial biased or angulated position is only a preliminary position and the fastener is capable of angulating even beyond if necessary. (Bush Decl. ¶¶ 24, 25.)

124. In reaching the foregoing conclusions, the Board, in its August 27, 2008 Final Decision, did not make reference to the following discussion in Carbone *et al.*'s Revised Motion 1 in determining whether Carbone *et al.* had argued that Carbone *et al.* had analyzed obviousness treating Invention (2) as prior art to Invention (1):

On the other hand, if Invention (2) were prior art to Invention (1), Invention (1) would nevertheless be patentable and unobvious over Invention (2) because, without the necessity of altering the essential nature of a cylindrical coupling member so that it has two separate bores with two independent longitudinal axes, one would still be able to achieve the desirable objects of the present invention; namely, greater angulation of the screw member *vis-à-vis* the coupling element. (Bush Decl. ¶ 29.) This is accomplished by merely altering the plane of at least one of the first and second ends of the coupling element so that they intersect each other, as shown, for example, in Figs. 1 and 3 of the Biedermann application. This invention is therefore capable of producing these results while sacrificing strength by removing material in exchange for the ease of manufacture of this invention. With this single bore system having a single longitudinal axis, when the fastener is placed in an angulated position in this coupling element, the fastener axis is not coaxial with that of the single bore. This exposes more of the spherical head of the screw, consequently providing for less surface area contact between the spherical head and the screw seat in the coupling element. The forces tending to pull the fastener away from the coupling element would thus act not only to pull the fastener away, but also to torque the fastener with respect to the coupling element. This leads to the reduction in overall strength discussed above. (Bush Decl. ¶ 23.) The strongest possible position of Invention (1) is when the fastener is not angulated, *i.e.*, the fastener is coaxial with the single axis of the coupling element construct.

125. In the August 27, 2008 Final Decision, the Board rejected Carbone *et al.*'s assertion that the Board overlooked the fact that Carbone *et al.* had in fact not only presented the closest prior art possible for the invention of Counts 2 and 3, but had specifically distinguished these counts over each other in view of the prior art.

126. Further in the August 27, 2008 Final Decision, the Board stated:

Substantively, we have reviewed Carbone Revised Motion 1 anew on a page-by-page basis for a discussion of the specific elements of each count as compared to those of the other and how the differences are such that the subject matter of one count would not have been obvious over the subject matter of the other. We continue to be unable to find such a discussion. Carbone Revised Motion 1 is focused on the generic "invention." That approach is singularly unhelpful when Carbone is charged with demonstrating patentable distinction between the two proposed counts.

(August 27, 2008 Final Decision 5:14-21.) The Board made this determination without reference to the discussions quoted above in paragraphs 123 and 124.

127. In its August 27, 2008 Final Decision, the Board went on to state:

The problem was and is that Carbone has failed [to] make the final, vital analysis — given the subject matter of one count why the subject matter of the other count would not have been obvious to one of ordinary skill in the art. That the subject matter of each count by itself is arrived at differently from the prior art, especially as it relates to the creation of angulation, does not begin to address the real issue. The real issue is, given the manner of creating angulation provided by one count, would the other way of creating angulation, as is specified in the other count, have been obvious?

That required analysis is simply absent. While Carbone discussed prior art that it considered to be the "closest prior art" to each of the complete inventions of the two counts at issue, it was in an incorrect context. Carbone failed to consider and discuss prior art relating to the features distinguishing one proposed count from the other, i.e., the coupling element. (*Id.*).

(*Id.* at 6:3-16.) The Board so stated without reference to the portions of Carbone *et al.*'s Motion 1 quoted in paragraphs 123 and 124.

128. In the August 27, 2008 Final Decision, the Board concluded that Carbone *et al.* had failed to address the knowledge of one skilled in the art both in Motion 1 as filed and in the Request for Rehearing. The Board did so without reference to its previous findings in

connection with Carbone *et al.*'s expert, Charles L. Bush, Jr., including the Board's conclusion that: "Given Mr. Bush's background, we conclude that he is qualified to testify as to the knowledge of one skilled in the art in the field of bone fixation assemblies at the time of the invention(s)." (Mem. Op. and Order 4:1-3.) Nor did the Board refer to its own prior findings of fact regarding a "personal of ordinary skill in the art":

004. Generally, the technology involved in this interference is directed to bone fixation assemblies to alter the alignment of adjacent vertebral bodies in the spinal column relative to one another.

005. In support of its motion, Carbone has submitted a declaration by Charles L. Bush, Jr., an Engineering Manager within the Cervical Division at Stryker Spine. (Declaration of Charles L. Bush, Jr., Ex. 2002, ¶¶ 1, 3, and 4).

006. According to the declaration, Mr. Bush received his Bachelor of Science degree in Industrial Engineering and Design from Montclair State University in 1986.

007. Mr. Bush declares that he has been working as a design engineer in the biomedical engineering field for about sixteen years. He states that he has worked for Stryker for more than four years, and as a manager during two of those years. Mr. Bush has worked as a Prototype Specialist of medical devices for four years and as a Design Engineer and Program Manager of disposable medical devices for twelve years. (Ex. 2002, ¶¶ 2-3).

008. At Stryker, Mr. Bush's responsibilities involve overseeing the design and implementation of different product lines for use in the cervical spine, designing and developing new products, and ensuring proper manufacture of existing products. Mr. Bush declares that he is a named inventor on patents and patent applications for medical devices, including invention directed for use in the spinal area. (Ex. 2002, ¶ 4).

009. Mr. Bush states that based on his experience working with biomedical engineers and orthopedic surgeons and neurosurgeons through 2001, he is familiar with the knowledge a person of ordinary skill in the field of medical devices had in 2002 and 2001. (Ex. 2002, ¶ 4).

(*Id.* at 3:2-27.)

129. In the August 27, 2008 Final Decision, in response to Carbone *et al.*'s contentions regarding the Board relying on a nonprecedential opinion, the Board asserted that its doing so was an acceptable practice at the Board.

130. Still further in the August 27, 2008 Final Decision, in response to Carbone *et al.*'s argument challenging the authority of the Board to decide the case, the Board directed Carbone *et al.* to Public Law No. 110-313, dated August 12, 2008, a date which was subsequent to the Board's April 30, 2008 Decision.

131. Finally, in the August 27, 2008 Final Decision, the Board denied the Request for Rehearing of Carbone *et al.*'s Substantive Motion 2 on the sole basis that it was contingent upon the granting of Carbone *et al.*'s Substantive Motion 1. In doing so, the Board made no reference to Carbone *et al.*'s arguments and suggestions that judicial economy favored the Board ruling on both of Carbone *et al.*'s motions after full briefing and on the merits.

THE PTO'S ERRORS

132. The APJ erred in declaring the Interference in the first instance by defining, as a single and sole count of the Interference, ten claims which included claims directed to two separate and patentably distinct inventions, which were not overlapping in scope, and which raised different issues as to compliance with 35 U.S.C. § 112, as well as different issues of patentability under 35 U.S.C. §§ 102 and 103.

133. The APJ erred in rejecting the list of proposed motions filed by Carbone *et al.* on November 29, 2007, and providing Carbone *et al.* less than four hours in which to submit a revised proposed motions list.

134. The APJ erred in issuing his December 6, 2007 Order, and in the oral rulings which preceded it, insofar as he refused to allow Carbone *et al.* to file a motion asserting that any claims of the Biedermann *et al.* '431 Application were unpatentable under 35 U.S.C. § 112, first paragraph, for lack of an enabling disclosure.

135. The APJ further erred in his December 6, 2007 Order, and in the oral rulings that preceded it, insofar as he refused to permit Carbone *et al.* to file a motion asserting that any of

the claims of the Biedermann *et al.* '431 Application were unpatentable under 35 U.S.C. §§ 102 and 103.

136. The Board erred in its January 22, 2008 Order insofar as it concluded that Carbone *et al.* had been given a full and fair opportunity in prior filings and conference calls to explain why they should be permitted to file a motion addressed to enablement of the Biedermann *et al.* '431 Application.

137. The Board erred in its January 22, 2008 Order insofar as it mischaracterized the arguments of Carbone *et al.* regarding the relationship between the sufficiency of disclosure of the '431 Application insofar as enablement is concerned and the sufficiency of disclosure insofar as written description is concerned.

138. The Board erred in its January 22, 2008 Order insofar as it held that Carbone *et al.* would have the burden of proving that the Biedermann *et al.* '431 Application lacked an enabling disclosure notwithstanding the fact that the claims at issue had been copied from the Carbone *et al.* '460 Patent.

139. The Board erred in its January 22, 2008 Order insofar as it affirmed the APJ's ruling precluding Carbone *et al.* from filing a motion addressed to the compliance of the Biedermann *et al.* '431 Application with the enabling disclosure requirement of 35 U.S.C. § 112.

140. The Board erred in its January 22, 2008 Order insofar as it affirmed the APJ's ruling that Carbone *et al.* could not file a motion directed to the patentability of Biedermann *et al.*'s claims over the prior art.

141. The APJ erred in his April 3, 2008 Order insofar as it relieved Biedermann *et al.* from responding to Carbone *et al.*'s Substantive Motions 1 and 2.

142. The Board erred in its April 30, 2008 Decision insofar as it denied the motion by Carbone *et al.* to redefine the Interference and replace existing Count 1 with proposed Counts 2 and 3.

143. The Board erred in its August 27, 2008 Final Decision in dismissing Carbone *et al.*'s Request for Rehearing based upon their purported failure to comply with 37 C.F.R. § 41.125(c) or Standing Order ¶ 125.2.

144. The Board erred in its August 27, 2008 Final Decision insofar as it reaffirmed the Board's prior denial of Carbone *et al.*'s motion to redefine the Interference as being directed to proposed Count 2 and proposed Count 3.

145. The Board erred in its August 27, 2008 Final Decision insofar as it held that Carbone *et al.* was guilty of procedural defaults in any or all of their original Substantive Motions 1 and 2, or their revised versions thereof, or their Request for Rehearing relating thereto.

146. The Board erred in its August 27, 2008 Final Decision in failing to sustain Carbone *et al.*'s argument challenging the authority of the Board to decide the case, in view of at least one member of the Board in this case having been appointed in violation of the U.S. Constitution, Article II, Section 2, clause 2, and in applying retroactively a statute, Pub. L. 110-313, that had been enacted on August 12, 2008, after the prior rulings in the Interference.

147. The Board erred in its August 27, 2008 Final Decision in failing to address Carbone *et al.*'s Substantive Motion 2 notwithstanding the fact that it had affirmed the denial of Carbone *et al.*'s Substantive Motion 1.

CLAIM FOR RELIEF

148. Paragraphs 1 through 147 are hereby incorporated by reference, as is fully set forth herein.

149. Each of the foregoing errors by the APJ and/or the Board render the actions of the PTO erroneous as a matter of law: arbitrary and capricious; an abuse of discretion; and/or not supported by substantial evidence.

150. Plaintiffs are dissatisfied with the decisions of the APJ and the Board within the meaning of 35 U.S.C. § 146.

151. This action has been timely filed.

DEMAND FOR RELIEF

WHEREFORE, plaintiffs demand judgment as follows:

1. Declaring that:
 - a. the claims at issue in the Interference at all times were and continue to be directed to two separate, distinct, and patentably distinct inventions, namely the inventions as to which Carbone *et al.* requested the APJ and the Board to redefine the Interference through proposed Counts 2 and 3;
 - b. Biedermann *et al.*'s '431 Application fails to comply with the enablement requirement of 35 U.S.C. § 112, ¶ 1, with regard to all claims corresponding to proposed Count 2.
 - c. Biedermann *et al.*'s '431 Application fails to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, with regard to all claims corresponding to proposed Count 2.
 - d. the claims of the Biedermann *et al.* '431 Application corresponding to proposed Count 3 are unpatentable under 35 U.S.C. §§ 102 and 103.
2. Awarding judgment to Carbone *et al.* and against Biedermann *et al.* on the basis that no claims of the '431 Application are patentable.

3. Remanding the case to the PTO and directing the PTO, the Board, and the APJ to:
 - a. reassign the Interference to a new APJ and a lawfully constituted panel of APJs;
 - b. redeclare and redefine the Interference by replacing Count 1 with Counts 2 and 3 as proposed by Carbone *et al.*;
 - c. allow Carbone *et al.* to file, and require all parties to fully brief, a substantive motion directed to whether the Biedermann *et al.* claims corresponding to proposed Count 2 comply with the written description and enablement requirements of 35 U.S.C. § 112, ¶ 1;
 - d. allow Carbone *et al.* to file, and require all parties to fully brief, a substantive motion directed to whether the Biedermann *et al.* claims corresponding to proposed Count 3 comply with the patentability requirement of 35 U.S.C. §§ 102 and 103.
4. An award of plaintiffs' costs and reasonable attorney fees.
5. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

By: 

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